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Medical Treatments of Unintentional Weight Loss in Long-Term Care: Including Current Issues Surrounding the Role of Medical Marijuana in Nursing Homes

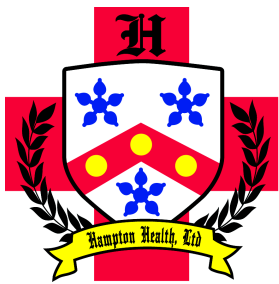
*by John H. Fullerton, MD, CMD, FACP, AGSF, FAAHPM et al
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From the days of %Reefer Madness+until the timing of Proposition 19 with the %legalization of Marijuana Initiative+on the ballot last November, the controversies swirling around not only the recreational use, but also the medical use of marijuana, particularly in frail, elderly geriatric patients with clinically significant weight loss (and cachexia), has been fraught with controversy. Even though the ballot initiative from 2010 went down in defeat on November 2, 2010, rumblings of some of the authors bringing another more %targeted+CA initiative in 2012 are regaining momentum.

It is therefore incumbent upon long-term care (LTC) facility medical directors, practitioners and our IDT colleagues- who care for our frail elders in our statesqpost-acute facilities- to understand the clinical, legal, and ethical ramifications of the commonly encountered medical %uses+of marijuana (including the synthetic derivative- Dronabinol).

In the summer of 2010, the California Society of Addiction Medicine (CSAM) went a long way toward assisting both clinicians and CA voters in both their understanding of the latest scientific evidence concerning CSAM's Position on the role of %Medical Marijuana+as well as the %Medical Aspects of Cannabis Legislation+prior to the November state elections re: the vote on state-wide legalization (labeled: %The Regulate, Control, & Tax Act of 2010+).

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Medical Treatments of Unintentional Weight Loss in Long-Term Care: Including Current Issues Surrounding the Role of Medical Marijuana in Nursing Homes

by John H. Fullerton, MD

From the days of "Reefer Madness" until the timing of Proposition 19 with the "Legalization of Marijuana Initiative" on the ballot last November, the controversies swirling around not only the recreational use, but also the medical use of marijuana, particularly in frail, elderly geriatric patients with clinically significant weight loss (and cachexia), has been fraught with controversy. Even though the ballot initiative from 2010 went down in defeat on November 2, 2010, rumblings of some of the authors bringing another, more "targeted" CA initiative in 2012 are regaining momentum.

It is therefore incumbent upon long-term care (LTC) facility medical directors, practitioners and our IDT colleagues who care for our frail elders in our states' post-acute facilities to understand the clinical, legal, and ethical ramifications of the commonly encountered medical "uses" of marijuana (including the synthetic derivative-Dronabinol).

In the summer of 2010, the California Society of Addiction Medicine (CSAM) went a long way toward assisting both clinicians and CA voters in both their understanding of the latest scientific evidence concerning CSAM's Position on the role of "Medical Marijuana" as well as the "Medical Aspects of Cannabis Legislation" prior to the November state elections re: the vote on state-wide legalization (labeled: "The Regulate, Control, & Tax Act of 2010").

Our clinical investigation should include an analysis of the scientific data to date behind the role of 9-Tetrahydrocannabinol (THC), the active ingredient in Medical Marijuana, as one of several potential orixigenic agents in the LTC setting, more and more being used to treat involuntary weight loss in frail elders. As with any other medication introduced into the rapidly growing frail, geriatric sub-population of long-term residents in this setting, medical indications need to be justified with each potential orixigenic agent and a traditional risk/benefit analysis, of course, needs to likewise be conducted in this sub-population of vulnerable patients within the LTC setting.

The specter of poor clinical outcomes in patients in the LTC setting directly related to unintentional weight loss (UIWL), defined as the loss of 5% of absolute body weight over 1 month or the loss of 10% of absolute weight loss over 6 months, looms large, particularly in the growing number of institutionalized patients over the age of 80 (with an annual incidence of involuntary weight loss of 30%-50% commonly quoted). Significant clinical sequelae commonly attributed to UIWL in the advanced elderly in LTC include: Increased post-operative complications, anemia, falls, fractures, pressure ulcers, a decline in ability to perform Activities of Daily Living (ADLs), probable Cytokine-mediated diminished host immunity (via TNF), as well as increased mortality.

It is important to point out that in the LTC setting UIWL is typically thought to be multi-factorial. For example, most advanced elderly institutionalized patients have at least one chronic co-morbidity-such as Cardiovascular (CV) Disease, Hypertension (HTN), or Chronic Kidney Disease (CKD) resulting in a restricted diet and/or fluid intake which can lead to decreased oral intake. Depression, Polypharmacy, and various commonly encountered medication side-effects can cause various degrees of decreased oral intake as well; for example, medications such as ACE Inhibitors, Quinolones, and Metronidazole can cause dysgeusia; Cls and SSRIs can cause nausea, vomiting, and diarrhea; Psychoactive agents like antidepressants, anticonvulsants, antipsychotics, and Medical Marijuana can cause increased sedation at meal times and poor by mouth (PO) intake. Other causes of weight loss in the institutionalized elderly due to decreased PO intake include: Dental/periodontal problems, cognitive and functional impairments, difficulty with self-feeding, and dysphagia/gastro-esophageal dysmotility problems. Another disorder related to age-related dysregulation of food intake includes: physiologic anorexia/cachexia of aging, which likely represents an inter-relation between changing levels Cholecystikinin, Leptin, and probably other humeral agents.

The evaluation and treatment of UIWL in the LTC setting includes a comprehensive approach, featuring screening, assessment, and potential orixigenic medication treatments; treatment typically involves adequate supplementation and hydration, but often orixigenic agents-like Dronabinol-are administered with clear-cut risks along with very little proven long term LTC scientific benefit to fall back on.

It is important to point out that from the days of Reeper Madness through the passage of Proposition 215 in California in 1996-as one of the first states to legalize the use of Medical marijuana-(entitled: The Compassionate Use Act-allowing state-wide medical use of Marijuana) through the recent attempt at passage of the statewide initial legalization act of 2010, there are no long term, placebo-controlled, double-blinded trials with significant numbers of frail, advanced elderly patients conducted in the LTC setting to date convincing practitioners to utilize any of the commonly encountered orixegenic agents-including Medical Marijuana-thus far. In fact, A Pub

Med search of the literature from 1956 until present regarding five of the most commonly encountered orexigenic agents, including Dronabinol [Rudolph 2001].

Dronabinol, a synthetic form of Delta 9-THC, an active ingredient in *Cannabis sativa* (or marijuana), has been studied and found generally to have both anti-emetic and appetite stimulant properties as well and as demonstrated to show improvements in both pain scores and in mood. In fact, studies abound outside of the LTC setting showing its efficacy in treating advanced AIDS/HIV Wasting, for example, as well as the Cancer Cachexia that occurs with advanced cancer patients, particularly in those patients undergoing chemotherapy with increased nausea and vomiting-secondary to Cis-Platinum-based drugs [Amar 2006, Aoyama, 2005].

In the few studies in elderly dementia patients, there were very few patients (15 in one six-week study and 28 patients in another placebo-controlled crossover design study of twelve weeks) who were studied and over brief treatment periods of twelve weeks or less. In the original study of elderly demented patients who displayed food refusal [Volcier 1997], even though a minimal (1.5 lbs) but statistically significant improvement in weight gain was noted as compared to placebo, interestingly enough, there was no statistically significant difference in total caloric intake between the two groups. In reality, in the Dronabinol treated group there were decreased behavioral disturbance and a corresponding increased sedentariness which the modest weight gain was subsequently most likely attributed to. Consequently it was unclear if the weight gain was from a decrease in overall activity levels and secondary decreased energy expenditure versus the effect of the THC treatment itself.

In the second study evaluated: An observational, retrospective pilot study of 28 subjects with anorexia and clinically significant weight loss over a 12 week period, fifteen subjects (ie: 53.5%) gained weight on Dronabinol with a weight gain of 3 +/- 8 pounds; unfortunately, these numbers were not found to be statistically significant as 11 of the subjects actually lost weight on Dronabinol [Wilson 2006].

The other traditional orexigenic agents administered in LTC that were evaluated included: Mirtazepine (Remeron), Cyproheptadine (Periactin), Oxandrolone (Oxandrin), and Megace. Cyproheptadine an anti-histamine used as an appetite stimulant in nursing homes is not surprisingly plagued by vexing and at times dangerous and predictable side effects, including: Confusion, dried mouth, blurred vision, urinary retention, constipation, tachycardia, and delirium. Importantly, there have been no LTC studies showing its efficacy in treating UIWL. Of note, this agent has also been studied for weight loss in cancer and anorexia nervosa patients outside the LTC setting, showing some benefits.

Mirtazepine, an SSRI, SNRI is a well known medication used to treat depression as a non-activating antidepressant. It has, however, widely become known as the orexigenic agent to consider in geriatric LTC patients with both anorexia and

dysthymia (particularly with co-existing vegetative symptoms of insomnia). In one non-LTC study of Remeron in dysthymic patients, a trend in weight gain was noted; unfortunately, the degree of weight gain was likewise not felt to be statistically significant [Howland 2008]. Subsequently, there were no differences found for this treatment purpose when compared to other SSRI's/SNRI's [Goldberg 2003, Mihara 2005]. Of note, there are once again no large, double blinded, placebo-controlled trials in long-term care performed to date.

Oxandrolone (Oxandrin) is a synthetic anabolic steroid (with properties of both Testosterone and Growth Hormone) that helps to restore lean body mass and replenish visceral protein stores; it is the only agent approved by the FDA for treatment of cachexia/sarcopenia. Even though there is evidence that the majority of patients with weight loss and chronic pressure ulcers experienced significant wound healing over a twelve week treatment period [Demling 1998], no studies that specifically address the use of this agent in the nursing home population have been conducted. There are also many contraindications to its use, including: patients with prostate or breast cancer as well as caution in patients with liver or kidney disease; it may additionally lead to troublesome hirsutism and fluid retention.

Megesterol Acetate (Megace) is a Progestational agent with a strong impact on appetite. Megace was originally used in contraception but its widely acknowledged effect of weight gain led to its common use as an orixigenic agent, approved, for example, by the FDA for HIV-Associated weight loss. Even though there are only nine studies in the long-term care setting with mixed results on its benefits at 200mg-800mg per day dosing schedules as an orixigenic treatment, its use in the LTC setting has gained widespread acceptance (in spite of its tendency to induce thrombosis in some of our most debilitated and sedentary residents in our nursing homes).

As a representative example of the LTC studies to date, interest in treating weight loss in nursing homes prompted Simmons, et al to conduct a non-randomized clinical trial to assess the effect of Megace on oral food and fluid intake [Simmons 2005]. Interestingly, the results of this study suggest that optimal feeding conditions may play a greater role on food and fluid intake than the use of Megace (or the 63 day study was too short and not at least 3 months in duration). Consequently, the question of optimizing feeding is more effective than the use of the most widely studied orixigenic in LTC-Megace. In contradistinction, "special" consideration at this time of a poorly studied orixigenic agent like THC in our frail, elderly and often demented LTC patients in this light therefore appears like a possibly "riskier proposition".

It is important to also emphasize that UIWL is anticipated in many End-Of-Life (EOL) patients as part of the dying process, particularly with advanced dementia diagnoses. Likewise, no role has been shown for the use of a PEG in this sub-population with dementia, where, in fact, the weight of the evidence shows no improvement in either

increased longevity or enhanced quality of life (QOL) [Wagner 2003] with Artificial Nutrition and Hydration in End-Of-Life Care. Instead, comfort feeding where the demented patient is simply offered food and fluids whenever they want them and provided whatever type of food and fluid preferred by the patient, never forcing the patient to feed or creating agitation has become the standard of care [NY Times Health Section August 2, 2010] entitled: Feeding Dementia Patients with Dignity. At times Prednisone may be used as a short term appetite stimulant and mood enhancer in this setting-keeping the calculated risk low; there are no studies, however, showing any role for orexigenics, including Medical Marijuana for these EOL patients in LTC.

Importantly, the California Society of Addiction Medicine (CSAM)-endorsed by the American Society of Addiction Medicine (ASAM) drafted a key position statement in the wake of the recent Proposition 19 ballot initiative re: Legalization of Marijuana, so that both voters and healthcare practitioners could be clued in to the current lack of the weight of the scientific evidence to date in the safety as well as in the efficacy of the use of Medical Marijuana (outside of the non-LTC setting usages concerning the treatment of AIDS/HIV Wasting Syndrome and as an alternative anti-emetic in some advanced cancer patients undergoing treatment with emetogenic chemotherapy agents) [CSAM 2010]; furthermore, the authors of the CSAM Position Paper had determined that the weight of the scientific evidence similarly troubled them re: several aspects of the current framework with which Marijuana is considered and distributed as medication in California, (whereby political lines versus valid medical lines of the discussion re: legalization arguments versus valid medical treatment arguments were prone to becoming blurred).

For example, according to the evidence presented by CSAM: there is no question Marijuana can be addictive; in fact, almost 10% of people who try it become dependent; moreover, Marijuana withdrawal symptoms can be intense, negatively affecting Quality Of Life and the ability to taper THC intake or to eventually quit; and finally, smoking forms of Marijuana is well-described to adversely affect health (not to mention definitively showing long-term cerebellar degenerative changes, for example, on serial imaging studies in the developing CNS of our younger patients < 27 years of age).

In an advanced elderly institutionalized population prone to UIWL, providing a psychoactive agent with no proven benefit in the long-term care setting, that may further cloud the sensorium, cause ataxia, and potentially cause a withdrawal syndrome within these fragile brains (with obvious seriously morbid or even life-threatening sequelae) has to be challenged in any risk/benefit analysis within this vulnerable sub-population in LTC. To compound matters further, in those health care providers and medical directors providing patient care in Federal facilities (like VA's) or in other states (or Districts) like Washington D.C. that have no similar compassionate use

local legislation allowing for the use of medical marijuana for wide-ranging purposes, the obvious legal prohibitions against prescribing in these regions or in those Federal institutions governed by current over-riding Federal Marijuana Laws: known as "The Controlled Substances Act" (which do not differentiate between recreational and medical uses of Marijuana). Needless to say, the DEA, the respective state/district medical board(s) and Federally-governed facility licensing agencies are often very serious about prosecuting violators.

Interestingly, the current political climate to legalize marijuana in thirty states including CA (which appears to also include advancing the use of medical marijuana embedded within this legislative agenda) seemingly paradoxically has rapidly become the pharmacological "Avatar" of our times; in fact, this "Green Day-type movement" has led to a plethora of serious research that has, in turn, has led to a "Pandora's Box" in the form of a much richer understanding of the "tonic-like" mechanism of our endo-cannabinoid system's broad, complex endogenous regulatory capabilities; in fact, this emerging field of endo-cannabinoid research appears to represent a vast, relatively untapped mine of potential, potent targeted therapies on the horizon.

Importantly, this ubiquitous system with specific Cannabinoid Receptors both inside and outside the CNS has myriad facets, according to the CSAM authors, including effects on: "Memory, pain, emotions, appetite, motor activity, digestion, attention, higher order executive functions, reward/addiction, the immune system, and reproductive activity" related to our extensive, endogenous endo-cannabinoid system; in reality, the CSAM authors point out that we should be excited about the prospects for bonafide, evidence-based, cannabinoid-based treatments for various maladies, such as: "Chronic pain, anxiety, spasticity, diarrhea, IBS, PTSD, nausea/vomiting of chemotherapy, as well as various wasting syndromes (possibly eventually even in our frail, advanced elderly, demented, institutionalized residents with poor po intake or those experiencing the "physiologic wasting/cachexia syndrome of aging."

In the meantime, based on the lack of scientific evidence surrounding the use of any of the aforementioned orixigenic agents to frail, geriatric patients in the LTC setting and the plethora of potential respective adverse effects in this sub-population, an appetite stimulant-like Dronabinol-should therefore only be chosen as a last resort in non-Federally owned and operated CA nursing homes, and probably not at all.

At the end of the day, it may be best to heed the pragmatic words of CSAM Position Paper's authors and likewise: "support a bifurcation of the two concepts of legalizing marijuana, leaving that question to the California (state) voters, and the leaving the question (re:) the medical value of cannabinoid-based medications (particularly in frail, advanced elderly LTC residents) to the FDA. We are convinced that eventually properly researched medications, with well-researched indications and side-effect

profiles will become available to physicians for use in the treatment of disease and the relief of suffering.

Ultimately, until we get to this point within our body of scientific enterprise, it would probably be wise to continue to employ the low-risk, "tried and true" approaches that derive from the comprehensive nutritional evaluation with rigorous supplementation, reserving the addition of the aforementioned orixigenic treatments only to very select patients when all conservative approaches have been exhausted. Even then, again, actively choosing THC as the orixigenic agent of choice with the available scientific evidence in our vulnerable geriatric patients who we treat with UIWL appears risky and speculative at best in this nursing home population.

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